NDA 20-829/S-011, S-012
NDA 20-830/S-013, S-014

Merck Research Laboratories
RY 33-720
P.O. Box 2000
Rahway, NJ 07065

02 AUG 2001

Attention: David Altarac, MD, MPA
Director, Regulatory Affairs

Dear Dr. Altarac:

Please refer to your supplemental new drug applications dated November 8, 2000, received November 9, 2000, and to your supplemental new drug applications dated March 21, 2001, received March 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Singulair Tablets (montelukast sodium) and Singulair Chewable Tablets (montelukast sodium).

We acknowledge receipt of your submissions dated April 17, 2001.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the addition of "myalgia including muscle cramps, and very rarely seizure; and very rarely pancreatitis; increased bleeding tendency, bruising; and edema " to the ADVERSE REACTIONS section of the package insert and "muscle aches, muscle cramps, seizure, pancreatitis, increased bleeding tendency, bruising and edema to the **What are the possible side effects of Singulair?** section of the Patient Product Information.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted April 17, 2001, patient package insert submitted April 17, 2001). Accordingly, supplemental applications N20-829/S-012 and N20-830/S-014, as amended, are approved effective on the date of this letter. However, At the next printing of the package insert and the Patient Product Information, revise "seizure" to "seizures."

Supplemental applications N20-829/S-0121 and N20-830/S-013 were superceded by N20-829/S-012 and N20-830/S-014, and are therefore acknowledged and retained.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research